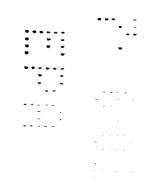
Aventis CropScience



454514-00

EPA Correspondence No. 01-07A July 3, 2001

Ms. Elizabeth Knee
Reregistration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202



Re: Response to the Report from the January 23, 2001 HIARC Meeting on Aldicarb

Dear Ms. Knee:

Aventis CropScience is providing a response to the February 8, 2001 report from the January 23, 2001 HIARC meeting on aldicarb. We believe our previous submissions regarding the three issues identified in the HIARC report were not thoroughly considered by the committee and we strongly object to the conclusions in that report. This response should provide all HIARC participants with a good background on what Aventis CropScience has already submitted to EPA to address the aldicarb issues identified in the February 8, 2001 HIARC report.

I am sending ten copies of our response so that you can distribute them to HIARC participants prior to the next meeting:

MRID Number 45451401

Tobia, A.J. 2001. Scientific Response to Issues Raised in the EPA's February 8, 2001 HED HIARC Report on the Re-evaluation of Aldicarb. Aventis CropScience, Research Triangle Park, NC. July 2, 2001. 289 Pages.

Concerning the 6(a)(2) information cited in the February 8 HIARC report, Aventis submitted neither the 5-day nor the 21-day dermal studies under this provision. Please provide references for the 6(a)(2) submissions being referred to in the HIARC report. In future HIARC reports we request that the Agency clearly identify all documents reviewed.

We could not fully address the points listed in Appendix I of the February 8, 2001 HIARC report as EPA has not provided us with DERs for all of the studies that were compared. Additionally, we are not able to follow Appendix I or determine the origin of all the studies. It appears to Aventis that single doses from various studies have been used out of context to support its position. Please provide a more detailed rationale and actual study titles and MRID Numbers so that we find the original documents that were presented at the January 23 HIARC meeting. Also, please provide the DERs for all studies compared in Appendix I.

The cholinesterase methodology used in both studies conducted by RTI has been validated and accepted by all international regulatory bodies. What is the Agency's concern in this area and what are the specific concerns for the methodology?

As it is important for EPA to fully understand the position of Aventis CropScience Gladicarb issues prior to the next HIARC and FQPA meetings, we would like to meet with EPA in July to fully discuss the issues and representations identified in the February 8 HIARC report. At this meeting we specifically request that the Reregistration Division be represented by Lois Rossi, Jack Housinger, and Elizabeth Knee and that HED be represented by Margaret Stasikowski, Linda Taylor, Whang Phang, Jess Rowland, Elizabeth Doyle, Christina Swartz and Vicki Dellarco.

Please phone me at (919) 549-2870 so we can set the date for the requested meeting.

Sincefelv.

Larry R. Hodges, Ph.D.

Registration Manager